PACKAGE LEAFLET: INFORMATION FOR THE USER Calcium Resonium[®] 99.934% w/w Powder for Oral/Rectal Suspension

calcium polystyrene sulfonate

Is this leaflet hard to see or read?

Phone 0800 035 2525 for help



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Calcium Resonium is and what it is used for
- 2. What you need to know before you use Calcium Resonium
- 3. How to use Calcium Resonium
- 4. Possible side effects
- 5. How to store Calcium Resonium
- 6. Contents of the pack and other information

1. What Calcium Resonium is and what it is used for

Calcium Resonium contains a medicine called calcium polystyrene sulfonate. This belongs to a group of medicines called 'ion exchange resins'.

Calcium Resonium is used to treat something called 'hyperkalaemia'. This is when there is too much potassium in your blood. It works by removing this extra potassium to bring your levels back to normal. It is often given to people who have kidney problems and people on dialysis.

2. What you need to know before you use Calcium Resonium

Do not use Calcium Resonium if:

- \times You are allergic to calcium polystyrene sulfonate or any of the other ingredients in this medicine (listed in section 6).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × You have been told that you have a low level of potassium in your blood
- × You have been told you have problems that result in high levels of calcium in your body such as thyroid problems or some types of cancer
- × Your gut is partially or completely blocked (obstructive bowel disease)
- × You are taking a sweetener called sorbitol (a «sugar-free» sweetener used to sweeten food). This is because taking sorbitol and Calcium Resonium at the same time can cause narrowing of the gut wall (gastrointestinal stenosis)

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and reduced blood flow to the gut wall (intestinal ischemia) causing severe damage to your gut (necrosis and perforation). You must not take any sorbitol whilst using Calcium Resonium.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Calcium Resonium.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Calcium Resonium if:

- ▲ You have abnormal bowel movements due to your medical condition (including conditions after surgery or drug usage) as these may cause a variety of disorders including bloating, severe constipation, reduced blood supply to your gut or ruptured bowel
- ▲ It is for your baby, and they were premature, had a low birth-weight or have reduced gut movement

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Calcium Resonium.

Other medicines and Calcium Resonium

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Calcium Resonium can affect the way other medicines work. Also some medicines can affect the way Calcium Resonium works.

In particular, check with your doctor if you are taking the following medicines:

- Medicines that contain salts such as magnesium, potassium or calcium. Ask your doctor if you are not sure
- Some medicines for constipation (laxatives) that contain magnesium
- · Some medicines for indigestion (antacids) that contain magnesium or aluminium
- · Digoxin or similar medicines from digitalis for heart problems
- · Levothyroxine or thyroxine for an under-active thyroid
- Lithium for mental illness

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Calcium Resonium.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine.

Calcium Resonium contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 15g dose, that is to say essentially 'sodium free'.

3. How to use Calcium Resonium

Your doctor or nurse will normally give you this medicine. Always use this medicine exactly as your doctor has told you. Check with you doctor if you are not sure.

The recommended dose is:

- The dose will depend on the results of blood tests
- For children the dose is also worked out according to how much the child weighs

Having the medicine

- Calcium Resonium can be given by mouth or put into the back passage (rectum)
- If given by mouth the powder can be swallowed with a little water or be made into a paste with something sweet, such as jam or honey
- It should not be mixed with fruit juice, this will stop the medicine working properly
- If given by mouth, it is important to sit up while taking the medicine so that you do not breathe in any powder into your lungs
- If given by the back passage you should try to keep the medicine in your back passage for at least 9 hours. Then it needs to be thoroughly washed out

How much is normally given: Adults (including the elderly)

By mouth

- The usual dose is 15g (one spoonful) three or four times a day
- Use at least 3 hours before or 3 hours after other oral medicines you may be taking. If you suffer from gastroparesis (a condition where your stomach can't empty itself in the normal way), leave at least 6 hours

before or after taking other medicines

Into the back passage

• The usual dose is 30g (two spoonfuls) once a day

In some cases, the medicine may be given both by mouth and into the back passage. This is where your potassium levels need to be lowered more quickly.

Children

If your child cannot take the medicine by mouth, it may be given into the back passage.

- The daily dose is 1g for each kilogram of bodyweight
- Once the medicine has started working the dose may be lowered to 0.5g daily for each kilogram of bodyweight

New-born babies

Calcium Resonium is only given into the back passage

• The daily dose is between 0.5g and 1g for each kilogram of bodyweight It is important to give the right dose for children and babies. If too much is given, children and babies could get serious constipation.

If you use more Calcium Resonium than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will be checking your progress, and checking the medicine that you are given. Ask them if you are not sure why you are getting a dose of medicine.

• If you are given too much Calcium Resonium the following effects may happen:

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- · Feeling irritable or confused
- Being unable to concentrate
- · Muscle weakness and poor reflexes leading to paralysis
- Breathing problems
- Faster or pounding heartbeat
- Muscle cramps

If you forget to use Calcium Resonium

Your doctor or nurse will give instructions about when to have your medicine. It is unlikely that a dose will be missed. If you think that you may have missed a dose, talk to your doctor or nurse.

If you stop using Calcium Resonium

Keep using Calcium Resonium until your doctor tells you to stop. If you stop using Calcium Resonium, your illness may come back.

Blood Tests

Your doctor may do regular blood tests while you are taking this medicine. This is to check the levels of salts (potassium, sodium, calcium and magnesium) in your blood.



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If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell a doctor or nurse straight away if you notice any of the following serious side effects:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Severe stomach pain, rectal pain
- Bloating, severe constipation
- · Severe nausea and vomiting
- Black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds
- Blood in your sick (vomit)

Talk to your doctor or nurse if you get any of the following side effects:

- Feeling tired, confused, having muscle weakness, cramps or a change in heart rate. These may be due to having low levels of potassium in your body
- Feeling jittery, having fits or muscle cramps. This may be due to low levels of calcium or magnesium in your body
- · Increased thirst or needing to go to the toilet more often
- High blood pressure, kidney problems, heart problems or swelling in your limbs. This may be due to high levels of sodium in your body
- Stomach upset, pain in your gut, narrowing or blockage of the gut
- Reduced blood flow to the gut wall causing severe abdominal (tummy) pain, or collapse
- Loss of appetite

- Feeling sick, being sick, constipation or diarrhoea
- Feeling short of breath or coughing. This could be the first sign of a serious chest infection. This can be caused by accidentally breathing in this medicine

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcium Resonium

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it. Store in a dry place.

Do not use Calcium Resonium after the expiry date which is stated on the container. The expiry date refers to the last date of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Calcium Resonium contains

- 99.934% w/w of the active substance, calcium polystyrene sulfonate
- The other ingredients are saccharin, vanillin and sodium.

What Calcium Resonium looks like and contents of the pack

Calcium Resonium is a cream or light brown coloured, fine powder. It is supplied in containers of 300g with a 15g scoop.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK Tel: 0800 035 2525 email: uk-medicalinformation@sanofi.com

Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor, nurse or pharmacist.

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